Written Testimony
Frank R. Lautenberg Chemical Safety for the 21st Century Act

Senate Environment and Public Works Committee
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Mr. Chairman and members of the Committee on Environment and Public Works, it is my honor to testify today about the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a bill to reform the Toxic Substances Control Act. I dedicate this testimony to the memory of Frank Lautenberg and his commitment to making chemicals safer for this generation, and future generations.

I am Dean of the Milken Institute School of Public Health at the George Washington University. I am a pediatrician and an epidemiologist and from 1993 through 1998 I served as Assistant Administrator for Prevention, Pesticides and Toxic Substances at the US Environmental Protection Agency (EPA). (This is now known as the Office of Chemical Safety and Pollution Prevention. While serving in that position I was responsible for the implementation of the Toxic Substances Control Act. Prior to joining the EPA I worked for eight years in public health with the California Department of Health Services. However, my testimony represents my own views and not the views of these or any other organizations.

When TSCA was passed in 1976, there were great expectations that it would improve our understanding of chemical risks and address these risks in a comprehensive multi-media framework. But, for a variety of reasons, TSCA has not been able to fully live up to these expectations. The people in the Toxics program at the EPA do an excellent job with the tools that they have but they have neither the legislative tools nor the resources that are needed.

There are several symptoms that all is not well with TSCA. First is the rising tide of chemicals being regulated on a state-by-state basis. While I support the right of states to take action to protect their citizenry, only federal actions protect all US citizens. Moreover, state actions too often leave us with replacement of a risky chemical by another chemical about which we know little or nothing. Second is the enormous gap that is forming between TSCA and the new chemicals legislation (REACH) in the European Union. And third is the dwindling away of personnel and resources in the EPA devoted to core TSCA efforts.

Today, I will discuss a number of concerns, most of which I have been trying to bring to your attention for the 21 years since the first time I testified about the pressing need for TSCA reform in May 1994. I will address these issues in the context of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, or Lautenberg Act. These include: risk evaluation, protection of vulnerable populations, risk management, precaution, new chemicals, right to know, pollution prevention, international management of chemicals and priority-setting.

Precaution

The current safety standard in TSCA, “unreasonable risk”, has been interpreted by the courts to mean that any decision to protect public health and the environment must be

balanced by the costs to industry. One reason that I was supportive of the Chemical Safety Improvement Act, or CSIA, in 2013, is that it explicitly required that decisions be based "solely on considerations of risks to human health and the environment." The Lautenberg Act goes even further in precluding EPA from using non-risk factors in making safety determinations.

Protection of Vulnerable Populations

TSCA does not require the protection of sensitive populations, including children. Several other statutes, the Clean Air Act, the Safe Drinking Water Act and the Food Quality Protection Act all contain provisions making it clear that such populations should be protected.

Children are often more highly exposed to chemicals in the environment, via diet, inhalation, crawling on the floor, mouthing hands and objects in the environment, and route such as transfer from other to baby in utero or in breast milk. Children are often more susceptible. "Windows of exposure" during development cause susceptibly to irreversible effects like birth defects, neurobehavioral outcomes, and other developmental alterations, and cancer.

Because the fetus and child are often more exposed and can be more susceptible to adverse effects of chemicals during critical life stages, this is a particularly important vulnerable group. Other groups include people who have genetic differences in response or metabolism of chemicals; the elderly, and people with preexisting conditions.

I am pleased that the Lautenberg Act explicitly requires that infants, children, pregnant women and the elderly be protected and clearly requires that both heightened susceptibility and unique exposure patterns be considered.

Risk Evaluation

To evaluate risk requires the availability of data on hazards and exposures. The Chemical Testing Program at EPA was established to carry out the policy expressed in TSCA that adequate data should be developed with respect to the health and environmental effects of chemical substances and that the development of these data should be the responsibility of chemical manufacturers and processors. Unfortunately, the analytic burden required of EPA to write TSCA 4 Test Rules and to defend them from litigation is substantial. As a result, over the past three decades, the Government Accountability Office (GAO), the Congress, and others have noted a lack of productivity and the absence of a clear agenda for testing.

EPA has tried to overcome this problem in a number of ways, including: use of Enforceable Consent Agreements rather than test rules; development of a Master

Testing List and voluntary approaches for screening high volume chemicals in cooperation with the chemicals industry and the OECD (Organization for Economic Cooperation and Development). These voluntary programs are good programs but it is not at all clear how and when EPA will move from screening to more extensive testing of chemicals for adverse endpoints.

Another important information gathering provision is TSCA Section 8(e), a critically important information-gathering tool that serves as an "early warning" mechanism for keeping the Agency apprised of significant new chemical hazards and exposures, and for satisfying the public's right to know about these hazards. EPA's longstanding policy has been, appropriately, that if certain serious health effects are discovered, that information should be considered for immediate reporting to EPA without further evaluation. Over and over again, across the decades, it comes to pass that companies may misinterpret TSCA Section 8(e) and EPA's corresponding policy.

EPA has tried to remedy this situation in several ways including by providing guidance documents and via the voluntary Compliance Audit Program (CAP) which, in 1992, allowed participating companies to submit delinquent Section 8(e) information and pay stipulated penalties up to a $1 million ceiling. Yet, this problem has recurred again and again. Some recent examples of significant information being withheld from EPA include: chromium, diacetyl and PFOA.

EPA collects little to no information about chemical exposures yet such information is essential to the evaluation of risk. TSCA needs to be reformed to give EPA clear expectation for testing of risks of existing chemicals. Both the CSIA and the Lautenberg Act would give the EPA very important authority to use orders to require testing and eliminate the current risk finding requirement. Significantly, the Lautenberg Act has enhanced EPA authority in this area (compared to the CSIA) by ensuring EPA can require testing of new chemicals and to inform prioritization.

The Lautenberg Act in my view unnecessarily requires that the EPA first request voluntary information prior to issuing an order. I think that this is an unnecessary step that could delay provision of information when different companies make different decisions about how and when to respond to voluntary requests. I would suggest that this provision be reconsidered.

Risk Management

In terms of managing the risks of toxic chemicals, the EPA never has recovered from the Fifth Circuit Court of Appeals decision to remand the 1989 Asbestos Ban and Phaseout Rule to EPA. In this case, the court's decision imposed a burden of proof on EPA that significantly increased the level of analysis on potential substitutes and on identifying the least burdensome approach for any future Section 6 action. The court's

interpretation of least burdensome alternative under Section 6 appears to define end-of-pipe solutions, where toxic substances are controlled after they are distributed into the environment, as less burdensome than pollution prevention solutions, where toxic substances are reduced or eliminated at their source. End-of-pipe solutions are in conflict with the pollution prevention approach and are more costly over time.

Importantly, the Lautenberg Act (like the CSIA) requires that EPA restrict any chemical that does not meet the safety standard. Going further, the Lautenberg Act would assure the public that the restrictions imposed are sufficient to assure that the chemical meets the safety standard. The Act would also strike the "least burdensome" requirement and make clear that costs and benefits are to be considered only "to the extent practicable based on available information". It would replace the requirement for identification of the "least burdensome" approach with a process in which EPA would evaluate only alternatives that are deemed relevant and feasible. I support this. Too often today decisions are made about phasing out, or banning, a use of a chemical with complete ignorance of the risks of possible substitutes. An example is the phase-out of BPA in food containers and the concern today about a substitute, BPS. Under this law the EPA could have assessed a cluster of chemicals that are available for this use and the result would have more clearly benefited public health.

New Chemicals

Section 5 of TSCA requires that anyone who intends to manufacture or import a new chemical substance in the United States notify EPA 90 days before commencing that activity. The EPA's new chemicals program has over the years reviewed thousands of new chemical substances. In many cases EPA has made decisions to prevent risk before a harmful substance enters commerce. The U.S.'s new chemicals program is unique in that it requires review of chemicals prior to manufacture rather than prior to marketing as in most other countries with such systems. In contrast the EU REACH system requires registration of substances manufactured or imported in EU above 1 tonne per year. Because many chemicals that initially are manufactured for research and development never come to market, the US gives the bulk of attention to new chemicals that will never appear in commerce.

The new chemicals program in the United States does not require any testing prior to submission of a "pre-manufacturing notification" (PMN) and over half of all PMNs are submitted without any test data. The Agency has developed tools to use Structure Activity Relationships (SAR) to predict and assess the fate and effects of new chemicals. SAR is limited so it is important that EPA can obtain test data on new chemicals.

When EPA determines that there is a risk associated with a PMN it has tools that can be used to manage those risks. TSCA Section 5 gives EPA the ability to require additional tests or other measures such as disposal controls and worker protection. These

provisions have caused the industry to screen out "bad actors" before presenting them to the EPA in the first instance.

The Lautenberg Act is a great improvement over TSCA in requiring an affirmation of safety by the EPA rather than triggering manufacture of the chemical by default if EPA is silent during the 90-day review. It establishes a clear expectation that new chemicals will be managed to provide reasonable assurance they will meet the new public health standard. Importantly it authorizes the EPA to suspend review and/or take intermediate action in the face of inadequate information to make a final decision. Additionally I suggest that Congress consider focusing EPA's efforts on premarket rather than premanufacture approvals so that EPA would be able to give more attention to chemicals that actually are entering commerce.

Right to Know

Empowering the public with information is a powerful tool for environmental progress. The creation of the Toxics Release Inventory (TRI), established in Section 313 of the Emergency Planning and Community Right-to-Know (EPCRA), led the way to a new era of public disclosure and a more constructive dialogue between citizens and industry on emissions reduction and pollution prevention. Likewise, in California, the right-to-know aspect of Proposition 65 has been a powerful tool for changing the formulation of chemical products on the market. Public release of environmental data gives everyone the ability to participate in the broader national effort to set an agenda for toxics and to address chemical issues based on the extent of risk posed. States, local governments, industry, labor unions, public interest groups and grass roots communities have important roles to play; all problems of chemical management cannot be solved through direct EPA action. Importantly, the Lautenberg Act would not preempt State actions requiring reporting, monitoring or other forms of information collection or disclosure.

As a former state regulator, I know the value of site-specific information in risk assessment and priority setting. Currently, TSCA does not allow EPA to share "confidential business information" or CBI with state officials. A large amount of information reported to the EPA under TSCA information is claimed as CBI; EPA's studies have found that much of this is either outdated or never deserved this protection in the first place. For example, in 1998 EPA found:

- More than 65 % of the information filings directed to the Agency through TSCA were claimed as confidential.
- About 20 % of facility identities in the inventory update were claimed as confidential.
- About 40 % of Section 8(e) substantial risk notices had chemical identity claimed as confidential.

As you might guess, if the EPA can't tell governors or state agencies what the chemical is, or where it is, the chemical with "substantial risk" cannot be addressed in any form or fashion.

The Lautenberg Act places stricter limits on the ability of companies to hide the identities of chemicals, and would review the CBI claims for all existing substances on the inventory in five years, so that these claims will not exist in perpetuity. It retains the provision in current law making health and safety information off-limits for CBI claims. It requires all chemical identity claims to be approved by EPA and claims automatically expired, unless renewed, after ten years. Further the law specifically provides for disclosure of information to states and others for need the information to protect health and the environment.

Priority Setting and Deadlines

Because there are so many chemicals on the market that have yet to be evaluated, what is needed is for Congress to set a clear agenda for priorities in evaluation and management of chemicals, as well as clear expectations for action. Along these lines, there are many chemicals that are strongly suspected to have potential risks, several of which have already been identified by the EPA. It would be a mistake to hamstring the agency with requirements to do comprehensive assessments and reassessments of all chemicals before any action is taken; it makes much more sense to establish an orderly process that is driven by prioritization.

The current bill does establish clear expectations and deadlines for the major components of a logical process involving prioritization, safety assessment, and regulation. It appropriately establishes a two-year transition period during which the EPA is to promulgate all new requirements and procedures, and allows the EPA to continue to do its work using existing procedures until these new procedures are in place. It requires EPA to place at least 10 chemicals on its high-priority list and 10 on a low-priority list and to have listed 20 of each within three years and 25 of each within five years.

I applaud the general approach in terms of requiring prioritization and agenda setting for safety assessment and regulation. However I think that Congress could set a faster pace for EPA to prioritize chemicals, to complete assessments and to manage chemical risks.

A more aggressive process would more quickly identify the several hundred chemicals that are in most need of control, as well as many more that would be determined to be low priority. In this regard, it is of critical importance that Congress make it clear that these assessments are not intended to be academic exercises but instead that they will prioritize the hazards and exposure scenarios that are most relevant to risk to human

health and the environment. Moreover, and obviously, too much focus on low priority chemicals would not be the best use of EPA's limited resources.

Fees

EPA's Toxics program has limited organizational capacity. Any new legislation will need to address this problem. It will be important to have a reasonable phase-in period, provision for fee-supports and clear and reasonable schedules. Current TSCA user fees apply only to new chemical notifications, are negligibly small ($2500, or $100 for a small business), and are retained by the general treasury rather than being made available to EPA to defray the costs of the program. The Act provides for much more generous fee collection for new and existing chemicals as well as those assessed as high priority. Fees would go to EPA and would be set at a level sufficient to cover 25% of program costs; Congress and EPA would not be allowed to use the fees to replace general revenues that currently support the TSCA program. I think that this is a good start to putting the program on a stronger footing and also, appropriately, to transfer some of the costs to the industry. I would like to see stronger consideration in factoring in inflationary increases so that the fees would not effectively decline over time.

International Management of Chemicals

Chemicals are increasingly managed internationally. TSCA needs provisions that allow the US to fully participate in international chemical management schemes. We, along with Iraq, Israel, Italy and Malaysia, have not ratified the Stockholm Convention on Persistent Organic Pollutants, signed by President George W. Bush in 2001. We, along with Angola, Iraq, Tunisia and Turkey, also have not ratified the Rotterdam Convention on Prior Informed Consent, signed by President Clinton in 1998. Yet the US was very much involved in negotiating these agreements.

Any legislative changes that would be required to allow us to join these conventions should be included. We need a provision that would trigger regulatory action when a chemical is added to the Stockholm Convention list of POPs identified for elimination or reduction, or to "opt out" of any such listing. We need an additional provision that triggers export notification for chemicals that are on the Rotterdam Convention mandatory PIC list. While similar amendments would be required in FIFRA, amending TSCA in these areas would be a good first step.

Regulatory Science

I caution against efforts to prescribe how the regulatory science is conducted or evaluated under TSCA. No matter how well driven by current scientific approaches, any specific approaches are likely to soon be outmoded. Rather, EPA needs to evolve its approaches over time, in recognition of the inevitable changing science behind chemical

evaluation and assessment as well as the regulatory options that might be available in the future.

I support the provisions of the Lautenberg Act that would allow this process to unfold in a context of scientific advances that are likely to improve our ability to assess chemicals over the next few years.

In that regard, I would not be supportive of amendments that attempt to enshrine in the law any current practices or even practices recently recommended by expert bodies. Current TSCA has been in place for nearly 40 years. This overhaul effort should not attempt to freeze the science in procedures that are recommended in 2015, but are almost certain to be outdated in just a few years time.

Preemption of State Authority

Under current TSCA, actions by EPA do preempt state and local actions, but states have the ability to obtain a waiver from Federal preemption to increase levels of protection in a state, if such an action does not unduly burden interstate commerce. The CSIA as introduced included strong preemption language that, as a former state public health official, concerned me. Specifically I was concerned that an EPA prioritization of a chemical, whether or not action was taken or even if the review were completed, would have a preemptive effect.

The Lautenberg Act is more reasonable. It saves all actions that states have taken prior to January 1, 2015 and it saves California's Proposition 65. It asks states to hold back on imposing new restrictions on chemicals while EPA is reviewing the chemicals. I don't think this is an onerous requirement. Most states do not have the capacity to review chemicals and those that do are not able to accomplish this quickly. Importantly this provision allows states to take action to control chemicals that EPA has determined to be low priority but for which a state may have concern for any reason. At any point in the process states will be able to request waivers from EPA and EPA's low-priority decisions are judicially reviewable by states. As noted earlier, the Lautenberg Act would not preempt State actions requiring reporting, monitoring or other forms of information collection or disclosure.

Conclusion

In summary, overhaul of TSCA is long overdue. Absent congressional action on TSCA we will continue to see the erosion of federal management of chemicals on many levels. This is a complicated area but at the end of the day there is one simple principle that should be kept foremost: assuring the American public that the products on the market, the air they breathe, the food and the water, are safe. Fortunately, at this time there is a major opportunity for reform.

I applaud the efforts by members of the Senate, the technical assistance from EPA, and the input that has been received from a number of stakeholder groups, including public health and industry groups. I understand that the Lautenberg Act is a work in progress. While many have been involved in shaping it, we are still in a process of producing a bill that can be enacted by both houses of congress.

Twenty-one years ago I didn't dream of a day when we would be this close to reform. Twenty-one years ago there were hearings, but everyone decided it was too complicated and everyone walked away for nearly a generation. At that time, the industry testified that TSCA was a model statute and that there was no need for reform. Most of the public health and environmental advocates who are here today were disengaged; they did not believe that anything could be done to reform TSCA.

I want to remind you of the human cost of inaction. Since TSCA passed in 1976, 149 million babies were born in this country. An estimated 3% of these babies had birth defects and more than 10% were born preterm. Since 1976, 86 million people in the US died; around 25% of these deaths were caused by cancer. Each of us has our own ideas about what a perfect TSCA would look like. But I don't want to be facing another Senate committee 20 years from now, testifying about a 60-year old law. Nor do I want have to tell my daughter that she and her future children will not have a greater level of protection because we failed to pass a good, even if not perfect, law.

The need for change is clear. We should not and cannot wait another generation before taking action. Thanks to you all for your efforts to bring the parties together to craft a reasonable, science-based and health protective overhaul of TSCA that will move us forward.